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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUNDGREN, JEFFREY S

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/044,899

Applicant(s)

ABBOTT ET AL.

Examiner

Jeff Lundgren

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 129-202 is/are pending in the application.
- 4a) Of the above claim(s) 129-143, 146, 147 and 155-202 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 144, 145 and 148-154 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 129-202 are pending in the instant application. Claims 129-143, 146, 147, and 155-202, are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention; the election was made **without** traverse in the reply filed on November 1, 2006. Claims 144, 145, and 148-154, are the subject of the Office Action below.

Oath/Declaration

The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR § 1.52(c).

Objection to the Abstract Under 37 C.F.R. § 1.72

The abstract of the disclosure is objected to because it does not allow the public generally to determine quickly from a cursory inspection the nature and gist of the claimed invention. Applicants should amend the abstract so that it closely corresponds to at least one independent claim. For example, Applicants should describe each of the claim elements in claim 144. See 37 C.F.R. § 1.72. Should Applicants amend the claims in their next reply, the amended abstract should take into account any further limitations added to the broadest independent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 145 and 148, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 145 and 148 are indefinite for reciting the phrase "said analyte is a member selected from the group consisting of vapors, gases and liquids," because these members are phases of matter, not analytes.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 144, 145 and 148-154, are rejected under 35 U.S.C. § 102(e) as being anticipated by Abbott *et al.*, U.S. Patent No. 6,284,197 B1, issued on September 4, 2001

Claim 144 is directed to a method for detecting an analyte, comprising contacting with said analyte a recognition moiety for said analyte, wherein said contacting causes at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation upon contacting said analyte with said recognition moiety; and detecting said second orientation of said at least a portion of said plurality of mesogens, whereby said analyte is detected.

Abbott discloses a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32).

“It has now been discovered that liquid crystals can be used to amplify, and transduce into an optical signal, the interaction of a wide array of molecules with various surfaces. The interaction of the molecule with the surface can be converted into an easily detected optical output.

A variety of surfaces, including spontaneously organized surfaces, can be designed so that molecules, on interacting with these surfaces, trigger changes in the orientations of films of mesogenic compounds. ***When the molecule interacting with the surface has a size on the order of a protein, the interaction can result in the***

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reorientation of approximately 10^5 - 10^6 mesogens per molecule. Interaction-induced changes in the intensity of light transmitted through the mesogenic layer can be easily seen with the naked eye.”

Abbott, col. 5, lines 13-26 (emphasis added); and:

“In a third aspect, the present invention provides a device for detecting an interaction between an analyte and a recognition moiety, said device comprising: a first substrate having a surface; a second substrate having a surface, said first substrate and said second substrate being aligned such that said surface of said first substrate opposes said surface of said second substrate; a first organic layer attached to said surface of said first substrate, wherein said organic layer comprises a first recognition moiety which interacts with said analyte; and a mesogenic layer between said first substrate and said second substrate, *said mesogenic layer comprising a plurality of mesogens, wherein at least a portion of said plurality of mesogens undergo a detectable switch in orientation upon interaction between said first recognition moiety and said analyte, whereby said interaction between said analyte and said first recognition moiety is detected.*”

Abbott, col. 14, lines 15-32 (emphasis added). Accordingly, claim 144 is anticipated.

Claims 150 and 151 are anticipated by Abbott’s teaching of “the interaction can result in the reorientation of approximately 10^5 - 10^6 mesogens per molecule” in the captioned paragraphs above.

Claim 152 is anticipated by Abbott’s teaching in Fig. 2 (see configurations of mesogenic compounds before and after analyte detection), and description thereof.

Claim 153 and 154 are anticipated by Abbott’s teaching of visual observation and/or microscopy (see Figs. 1C, and 3A-3I; and description thereof).

Further, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass or organic polymers (see col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; col. 15, line 59 thru col. 16, line 14; and Fig. 2).

The surface of the substrate disclosed by Abbott is patterned with features such as grooves and ridges with emphasis on the texture:

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"The nature of the surface of the substrate has a profound effect on the anchoring of the mesogenic layer which is associated with the surface. The surface can be engineered by the use of mechanical and/or chemical techniques. The surface of each of the above enumerated substrates can be substantially smooth. Alternatively, the surface can be roughened or patterned by rubbing, etching, *grooving*, stretching, oblique deposition *or other similar techniques known to those of skill in the art. Of particular relevance is the texture of the surface which is in contact with the mesogenic compounds.*"

Abbott, col. 16, lines 47-57 (emphasis added).

With regard to the size of the aforementioned, Abbott generally identifies certain techniques for creating these features and their scale:

"The *size and complexity of the pattern on the substrate is limited only* by the resolution of the technique utilized and *the purpose for which the pattern is intended*. For example, using microcontact printing, features as small as 200 nm have been layered onto a substrate. See, Xia, Y.; Whitesides, G., *J. Am. Chem. Soc.* 117:3274-75 (1995). Similarly, using photolithography, patterns with features as small as 1 μm have been produced. See, Hickman et al., *J. Vac. Sci. Technol.* 12:607-16(1994). Patterns which are useful in the present invention include those which comprise features such as wells, enclosures, partitions, recesses, inlets, outlets, *channels, troughs, diffraction gratings and the like.*"

Abbott, col. 17, lines 7-18 (emphasis added).

As in claim 149, Abbott teaches the following regarding recognition moieties and the analytes that bind to the recognition moieties:

"In another preferred embodiment, the recognition moiety is a biomolecule. In still further preferred embodiments, *the biomolecule is a protein, antibody, peptide, nucleic acid (e.g., single nucleotides or nucleosides, oligo nucleotides, polynucleotides and single- and higher-stranded nucleic acids) or a combination thereof*. In a presently preferred embodiment, the recognition moiety is biotin."

Abbott, col. 26, lines 30-36 (emphasis added); and:

"Recognition moieties which are antibodies can be used to recognize analytes which are *proteins, peptides, nucleic acids, saccharides or small molecules* such as drugs, herbicides, pesticides, industrial chemicals and agents of war."

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Abbott, col. 29, lines 10-22 (emphasis added). These samples meet the limitations of claims 145 and 148:

Claims 144, 145, and 148-154, are rejected under 35 U.S.C. § 102(b) as being anticipated by Gupta *et al.*, *Science* 279:2077-2080 (1998).

Claim 144 is directed to a method for detecting an analyte, comprising contacting with said analyte a recognition moiety for said analyte, wherein said contacting causes at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation upon contacting said analyte with said recognition moiety; and detecting said second orientation of said at least a portion of said plurality of mesogens, whereby said analyte is detected.

Gupta is considered cumulative to the disclosure of Abbott with regard to the presently claimed invention, and teaches a mesogenic liquid crystal biosensing device formed on an anisotropic surface with nanometer-patterned features. Gupta reveals:

“The principles of our approach are based on four properties of LCs (5). First, molecules within LCs (mesogens) can communicate their orientations to regions of the fluid that are up to 100 mm away. This long-range communication between mesogens permits ligand-mediated binding of proteins to surfaces to be amplified into changes in the orientations of 1- to 20-mm-thick films of supported LCs. Second, because mesogens within LCs have mobilities that are characteristic of liquids, information about the binding of ligands and receptors at surfaces propagates rapidly from the surface into the bulk of the LC (amplification and transduction can occur in a few seconds) (6). Third, *optical anisotropy caused by the preferred orientations of mesogens within LCs provides a straightforward way to transducer changes in the orientations of bulk LCs into optical signals that are easily read using ambient light and the naked eye.* Fourth, *because the orientations assumed by LCs near surfaces reflect the molecular level or mesoscale structure of a surface, surfaces can be designed such that the binding of both macromolecules and small molecules is amplified and transduced into optical signals.*

We designed surfaces with nanometer-scale topographies that could be erased by the specific binding of proteins to surface

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immobilized ligands (Fig. 1A), thus leading to macroscopic changes in the orientations of LCs supported on these surfaces.

Gupta, page 2077, second paragraph (emphasis added), and explains in the Abstract that binding of an analyte effects 10^5 to 10^6 mesogens. Gupta teaches two sensor formats, a first where biotin is attached to the sensing surface, followed by the mesogenic layer, and then introduction of the analyte for the detection of avidin; and a second where biotin is attached to the sensing surface and then FITC-avidin, followed by the mesogenic layer, and then introduction of the analyte for the detection of the anti-FITC antibody, of which has a bound surface thickness of 3.5 nm. Gupta teaches the detection of viruses as in claim 2 and 17 (page 2079, final paragraph).

Gupta illustrates the effects of the transduction phenomena in Fig. 2, and in Fig. 3A-3I, and accordingly meets the limitations of claims 145, 148-154.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either

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is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 144, 145, and 148-154, are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 6,852,285, either on its own, or in view of Gupta *et al.*, *Science* 279:2077-2080 (1998), because the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The express limitations of claims 144, 145, and 148-154 of the instant application, and certain teachings of Gupta have been detailed above, and are herein incorporated by reference.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter. Specifically, claim 1 of the '285 patent is directed to a method of visually detecting an analyte-recognition moiety complex, formed by an interaction between an analyte and a recognition moiety for said analyte, by transducing said interaction to an organic mesogenic layer, said method comprising: (a) interacting said analyte with a patterned surface comprising said recognition moiety, thereby forming an analyte-recognition moiety complex, said surface comprising: (i) a substrate; (ii) a self-assembled monolayer bound to said substrate; and (iii) said recognition moiety bound to said self-assembled monolayer; (b) contacting said analyte-recognition moiety complex with said organic mesogenic layer, thereby anchoring said organic mesogenic layer onto said self-assembled monolayer and causing at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation, thereby transducing said interaction to said mesogenic layer, said transducing causing said mesogenic layer to register a visually detectable feature; and (c) visually detecting said feature.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

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the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 144, 145, and 148-154, are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 6,284,197, either on its own, or in view of Gupta *et al.*, *Science* 279:2077-2080 (1998), because the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The express limitations of claims 144, 145, and 148-154 of the instant application, and certain teachings of Gupta have been detailed above, and are herein incorporated by reference.

Specifically, claim 1 of the '197 patent is directed to a method of visually detecting an analyte-recognition moiety complex formed by an interaction between an analyte and a recognition moiety for said analyte by transducing said interaction to an organic mesogenic layer, said method comprising:

- (a) interacting said analyte with a surface comprising said recognition moiety, thereby forming an analyte-recognition moiety complex, said surface comprising: (i) a substrate; (ii) a self-assembled organosulfur or organosilane monolayer bound to substrate; and (iii) said recognition moiety bound to said self-assembled monolayer;
- (b) contacting said analyte-recognition moiety complex with said organic mesogenic layer, thereby anchoring said organic mesogenic layer onto said self-assembled monolayer and causing at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation, thereby transducing said interaction to said mesogenic layer, said transducing causing said mesogenic layer to register a visually detectable feature; and
- (c) visually detecting said feature.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

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Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipso verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

JON EPPERSON
PRIMARY EXAMINER

